NextCure

Clinical Scientist

Company overview

NextCure is a growing clinical-stage biopharmaceutical company located in Beltsville focused on discovering and developing first-in-class immunomedicines for the treatment of cancer and other diseases. NextCure is committed to professional development in the context of learning, managing, and developing its employees. We create a unique environment for our employees, providing exposure to various facets of our operations cultivating career growth and development. We are excited about the ongoing work at NextCure and invite you to come join us in the culture and build your career in an environment that nurtures professional growth and development.

Role Summary

We are seeking a highly motivated Clinical Scientist who will be responsible for supporting ongoing clinical development of NextCure products. The candidate will play a key role in guiding different projects in support of product development, assisting with clinical trials, and contributing to all follow-up studies. The Clinical Scientist is responsible for support in the planning, implementation, and daily operation of drug development projects.

Responsibilities

- Participate in the preparation of abstracts for scientific meetings
- Conduct comprehensive literature searches for product/technology evaluations and writes ad hoc reports based on these literature searches towards regulatory submissions
- Oversee pharmacovigilance for clinical projects including detecting safety signal and providing scientific support in reviewing and reporting of AEs/SAEs and evaluating benefit/risk assessments
- Regularly review biomarker's analysis and plans for ongoing clinical trials
- Support and assist in the design and implementation of early and late-stage clinical projects
- Develop comprehensive scientific and medical content of all clinical programs
- Support the preparation of clinical development plans that integrate pre-clinical and early clinical findings
- Assist in drafting and presenting protocols and clinical development plans
- Participate and provide support to cross-functional teams, including clinical scientists
- Communicate with cross functional teams to ensure alignment in projects management throughout the phases of clinical development
- Work closely with the clinical development team to assess study progress, ensure proper study conduct and adherence to the protocol, and
- Closely work with Biostatistics to review, evaluate, and analyze data
- Provide updates on studies, interim results, and final headline data to senior management

- Assist in the preparation of clinical study core documents (protocol, investigator brochure, informed consent forms)
- Assist in preparation of various official and regulatory documents for Regulatory and other agencies, such as BLAs, INDs, drug safety reports, clinical study annual reports, medical reports, and any other documents to support the study design
- Proactively prepare responses to regulatory agencies regarding questions about complex clinical development issues (e.g., safety or efficacy)
- Participate in the implement of clinical policies, and SOPs
- Support clinical initiatives to improve the quality and content of all clinical programs
- Review cross-functional/organization processes as needed to effectively deliver results in our portfolio

Required education and experience

- PhD, PharmD, or MD
- 5+ years' relevant experience in pharma or biotech
- Oncology and immunology experience preferred
- 2-4 years of working in drug development programs with 2+ years in clinical development experiences at a pharmaceutical, biotechnology, or CRO company
- Experience working in drug development phases
- Working knowledge of FDA/EMEA requirements, good clinical practices, and pharmaceutical clinical development in oncology
- Ability to interact with investigators and CROs as a scientific representative
- Ability to operate independently with minimal supervision
- Ability to communicate to varied level audiences across the organization
- Ability to set priorities for team and maintain accountability
- Ability to balance scientific & business perspectives
- Demonstrate a strategic thinking and curiosity skills

Qualifications

- Demonstrated ability to manage multiple and diverse projects concurrently
- Organizational and project management skills
- Demonstrated ability to develop positive relationships and collaborations
- Strong analytical skills; a strategic thinker, planner, and implementer
- Solid scientific skills and attentive to details
- Working knowledge of biostatistics is a plus
- Good understanding of pharmacovigilance preferred

NextCure

NextCure is an Equal Opportunity Employer and offers a competitive salary and benefits package in a scientifically engaged team work environment.

Qualified candidates should email their resume to info@nextcure.com.